

Lastly, Applicants' agent wishes to thank the Examiner for the very helpful personal interview of February 8, 1995 regarding this application. The claims have been amended herein in accordance with the agreements reached during that interview.

### **AMENDMENTS**

The claims have been amended in accordance with the agreement reached during the Examiner interview on February 8, 1995. Newly added Claims 30, 31 and 32 are fully supported by the specification. In particular, the species of Claim 32 are supported by Examples 2, 3D, 4D, 5F, 6, 7C, 9E, 10, 15D, 16E, 17C, 18F, 19G 20, 21E, 22F, 23D, 24E, 25F, 28E, 30E, 31G, 32E, 39, 40, 41, 42, 44G, 45C, 47E, 48, 50D, 51G, 52G, 53F, 54D, 55D, 56C, 58G, 59G, 60D, 61D, 62D and 63. None of the amendments introduces new matter.

### **SECTION 112 OBJECTION AND REJECTIONS**

A. The Examiner has objected to the specification and rejected Claims 1-7 and 12-20 under 35 U.S.C. 112 (first paragraph). The Examiner states that the in vitro data provided in support of the asserted utility is not representative of all of the compounds claimed.

Applicants assert that the in vitro data provided in the specification (i.e., in vitro inhibition of HIV protease and inhibition of HIV infection in human cells) is representative of the genus claimed. The Examiner has provided no basis other than mere speculation for doubting that all of the claimed compounds have the asserted utility. Therefore, the Examiner should accept the Applicants' assertions as accurate and the Examiner should find patentable the full scope of the claims as amended herein.

While Applicants continue to assert that all of the claimed compounds have the in vivo activity disclosed and claimed, in an effort to advance the prosecution of this application, Applicants have cancelled by amendment herein Claims 13-14 and 16-17 (without prejudice to the patentability of the subject matter claimed therein and without acquiescence to the rejection). Applicants reserve the right to file a divisional application claiming the subject matter of the cancelled claims.

Applicants have maintained claims (i.e., Claims 12, 15, 30 and 31) relating to (1) pharmaceutical compositions comprising the compound of Claim 29 and (2) methods of using the compound of Claim 29. It is well established by human clinical trials that the compound of Claim 29 (also known as ABT-538) is useful for inhibiting an HIV infection. This assertion is supported by Ho, et al., Nature, Vol. 373, pages 123-126 (1995), a copy of which is submitted herewith. This article discloses that in HIV-infected patients treated with ABT-538 (the compound of present Claim 29), every patient had a rapid and dramatic decline in plasma viraemia over the first two weeks of treatment. This decline was equivalent to a 98.5% inhibition of the HIV infection. Furthermore, CD4 lymphocyte counts rose in each patient. In view of this data, Applicants assert that the compound of the invention which is encompassed by Claim 29 and Claim 8 has been demonstrated to be useful for inhibiting HIV protease and for inhibiting an HIV infection in vivo in humans.

B. The Examiner has further rejected Claims 1-7 and 12-20 under 35 U.S.C. 112 (first and second paragraphs) for the reasons of record. In particular, the Examiner states that the number of carbon atoms should be specified for each substituent. Applicants have amended the claims herein to include the number of carbon atoms in the substituents. These amendments are fully supported by the definitions present in the specification and do not introduce new matter.

Applicants have also amended the claims herein to include the definitions of "pharmaceutically acceptable esters and prodrugs" as they are found in the specification. These amendments do not introduce new matter.

C. Lastly, the Examiner has rejected Claims 8 and 29 under 35 U.S.C. 112 (second paragraph) as being duplicates of each other. Applicants assert that Claims 8 and 29 are not identical. Claim 8 relates to the compound named, as well as pharmaceutically acceptable salts, esters or prodrugs thereof. Claim 29 (as amended herein) relates to the compound named, as well as pharmaceutically acceptable salts thereof. Claim 29 claims a subset of the invention claimed in Claim 8. Therefore, Claim 8 and Claim 29 are not identical.

In view of the above, the Examiner is respectfully requested to reconsider and withdraw the Section 112 objection and rejections.

#### **OBJECTION TO CLAIMS 9 AND 10**

The Examiner has objected to Claims 9 and 10 as being dependent upon a rejected base claim. Applicants assert that Claims 9 and 10 are independent claims. Therefore, the Examiner is respectfully requested to reconsider and withdraw the objection to Claims 9 and 10.

#### **AMENDMENT OF INVENTORSHIP**

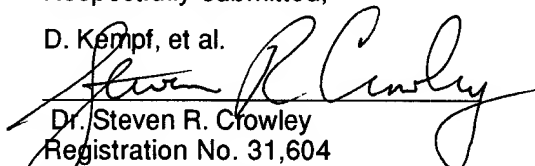
Please amend the inventorship in this application to delete the names of Thomas J. Sowin, Daniel S. Reno, Anthony R. Haight and Arthur J. Cooper as joint-inventors. A Petition to Correct Inventorship in accordance with 37 C.F.R. 1.48(b) is submitted herewith. The fee due pursuant to 37 C.F.R. 1.17(h) is authorized in the petition. Favorable action on the petition and amendment of inventorship is respectfully requested.

#### **ACTION REQUESTED**

In view of all of the above, reconsideration and allowance of Claims 1-10, 12, 15, 18-20 and 29 (as amended) and Claims 30-32 (newly added) and entry of the inventorship amendment are respectfully requested.

Respectfully submitted,

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